

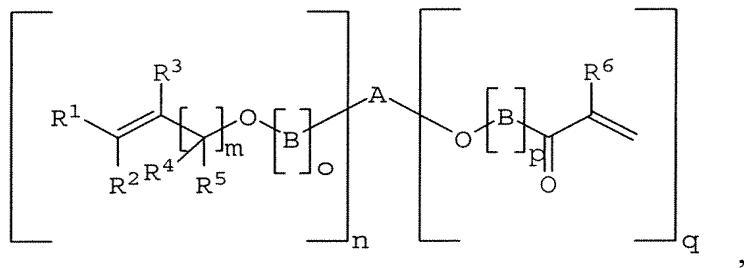
REMARKS

Claims 1-6 and 8-12 are pending in the application. Claims 1-4 and 6 have been withdrawn from the application as being directed to non-elected subject matter. New claims 13-18 have been added to the application. Therefore, claims 5 and 8-18 are at issue.

Support for new claims 13-18 can be found in the specification at page 17, lines 37-39; page 16, lines 35, 36, and 39; page 20, lines 32-33, and the examples.

Present claims 5, 9, and 10 recite a swellable hydrogel-forming polymer comprising a copolymerized (meth)acrylic ester as set forth in withdrawn claims 1, 2, or 3, respectively. Upon an indication of allowability, the structure in claims 1, 2, and 3 will be incorporated into claims 5, 9, and 10. The (meth)acrylic esters of claim 1, 2, and 3 serve as internal crosslinkers for gel-forming polymers. A (meth)acrylic ester is copolymerized with at least one hydrophilic monomer (specification, page 22, lines 13-16), which typically is acrylic acid and/or a salt thereof (specification, examples). Claims 8, 11, and 12 recite hygiene articles comprising a hydrogel-forming polymer.

An important feature of the claims is the use of an internal crosslinker having the following structure:



wherein R¹, R², R³, R⁴, R⁵, R⁶, m, n, o, p, q, A and B are each defined in the claims. Important features of the claimed internal crosslinkers are that the compound contains (a) *at least 3 ethylenically unsaturated groups*, i.e., n + q is an integer from 3 to 10, and (b) *two different ethylenically unsaturated groups*, i.e., allyl groups *and* acryl groups.

Claims 5 and 8-12 stand rejected under 35 U.S.C. §102(e) as being anticipated by WO 03/095496 (WO '496). Claims 5 and 8-12 also stand rejected under 35 U.S.C.

§102(b) as being anticipated by EP 0 997 507 (EP '507) or WO 01/00259 (WO '259) or WO 93/21237 (WO '237) or Gregorovich et al. U.S. Patent No. 6,080,816 ('816 patent) or Shen et al. U.S. Patent No. 5,854,386 ('386 patent) or Whitmore et al. U.S. Patent No. 6,417,425 ('425 patent) or Jonas et al. U.S. Patent No. 6,350,710 ('710 patent). Applicants traverse these rejections.

It is axiomatic that “[A] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). A determination that a claim is anticipated under 35 USC §102 involves two analytical steps. First, the Patent Office must interpret the claim language, where necessary, to ascertain its meaning and scope. In interpreting the claim language, the Patent Office is permitted to attribute to the claims only their broadest *reasonable* meaning as understood by persons having ordinary skill in the art, considered in view of the entire disclosure of the specification. *See In re Buszard*, 504 F.3D 1364 (Fed. Cir. 2007) (reversing a Patent Office decision that applied an unreasonably broad interpretation to a claim); *see also, In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997). Second, the Patent Office must compare the construed claim to a single prior art reference and set forth factual findings that “each and every limitation is found either expressly or inherently [disclosed] in [that] single prior art reference.” *Celeritas Techs. Ltd. V. Rockwell Int'l Corp.*, 150 F.3d 1354, 1360 (Fed. Cir. 1998). Additionally, “[t]he identical invention must be shown in as complete detail as is contained in the patent claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

Each of the above cited references differs from the present claims in at least one respect, thereby precluding an anticipation rejection under 35 U.S.C. § 102.

WO '496 discloses hydrophilic substances that can be used to modify biotechnological products and small molecule drugs (WO '496, page 2, lines 23-26). As stated by the examiner, the reference discloses an active carbohydrate attached to a polymer chain *via* a hydroxyl group and to an active linkage group. WO '496 fails to teach or suggest a swellable hydrogel forming polymer, and most importantly the reference fails to teach or suggest an internal crosslinker according to claims 1-3, which is requiring in pending claims

5 and 8-12. In particular, the compounds shown in the schemes of WO '496 have *only one* ethylenically unsaturated group.

Because the present claims recite a hydrogel-forming polymer having an internal crosslinker containing at least three ethylenically unsaturated groups and that must contain an allyl *and* an acryl group, differences exist between WO '496 and the present claims such that an anticipation rejection under 35 U.S.C. §102(e) cannot be maintained. In addition, WO '496 is not directed to hydrogel-forming polymers, but rather is directed to biologically active compounds.

EP '507 discloses a radiation curable ink (page 2, line 5). The reference is not remotely directed to a hydrogel-forming polymer. The radiation curable ink comprises an amino-functionalized polyetheracrylates, such as Laromer LR8869 (EP '507, page 3, lines 45-56). See Exhibit A, submitted concurrently with this response. The disclosed polyetheracrylates do not contain two different ethylenically unsaturated groups, i.e., allyl *and* acryl groups, as required in an internal crosslinker of the present claims. The disclosed polyetheracrylates also differ from the claimed internal crosslinker because they contain an amino group. The present internal crosslinkers do not.

Because the present claims are directed to a hydrogel forming polymer and EP '507 is directed to a radiation curable ink, and because EP '507 fails to disclose an internal crosslinker containing allyl *and* acryl groups, but containing an amino group, differences exist between the present claims and EP '507 such that an anticipation rejection under 35 U.S.C. §102(b) cannot be sustained.

WO '259 discloses hydrogel-forming polymers, and lists various internal crosslinkers at page 8, line 15 through page 9, line 5. One of the disclosed crosslinkers is allyloxy polyethylene glycol methacrylate (page 8, line 23). This crosslinker contains two different ethylenically unsaturated groups, i.e., an allyl and an acryl group. However, the disclosed crosslinker contains a total of only two ethylenically unsaturated groups, wherein the internal crosslinker of the pending claims require 3 to 10 of such groups.

In addition, allyloxy polyethylene glycol methacrylate contains a polyethylene glycol group between the allyl and acryl groups, i.e., repeating $-OCH_2CH_2-$ groups. The internal crosslinker recited in the pending claims contains an A moiety of C₃ to C₂₀ alk(n+q)yl or C₃ to C₂₀ heteroalk(n+q)yl, which is not present in an allyloxy polyethylene glycol methacrylate of WO '259.

Because differences exist between the presently claimed internal crosslinkers and the crosslinkers of WO '259, and particularly allyloxy polyethylene glycol methacrylate, an anticipation rejection under 35 U.S.C. §102(b) cannot be maintained.

WO '237 discloses hydrogel-forming polymers, and further discloses internal crosslinkers containing at least two ethylenically unsaturated groups. See WO '237, page 3, lines 3-14. However, the crosslinkers of WO '237 contains *only* acryl groups (page 3, lines 9-10), and fails to teach or suggest the additional presence of an allyl group, as required in an internal crosslinker recited in the present claims.

Because the present claims require the presence of allyl *and* acryl groups in the internal crosslinker of the claimed hydrogel forming polymer, a difference exists between the present claims and the WO '237 disclosure. Therefore, a rejection of claims 5 and 8-12 under 35 U.S.C. §102(b) as being anticipated by WO '237 cannot be sustained. In addition, and as discussed more fully hereafter, a hydrogel-forming polymer of the present invention containing the internal crosslinker of claim 1 was compared to a hydrogel-forming polymer crosslinked with a crosslinker of WO '937 and unexpected results were observed.

The '816 patent discloses coatings containing reactive silicon oligomers that cure to provide mar and etch resistant coatings ('816 patent, column 1, lines 5-9). The reference is not remotely related to hydrogel forming polymers, which are substantially different from the mar and etch resistant coatings of the reference. The compositions of the '816 patent contain an organic polyol polymer formed from hydroxyalkyl (meth)acrylates. This organic polyol polymer contains pendant hydroxyl groups for reaction with other components of the composition. The organic polyol polymer is prepared from a (meth)acrylate monomer, but the *sole* ethylenic unsaturation of the monomer is *consumed* when the organic polyol polymer is prepared. Therefore, the organic polyol contains *no*

ethylenically unsaturated groups (rather than the at least three recited in the claims). The '816 patent fails to teach or suggest hydrogel-forming polymers having an internal crosslinking agent containing an allyl and an acryl group.

Because of the above-discussed differences between the present claims and the '816 patent, a rejection of claims 5 and 8-12 as being anticipated by the '816 patent cannot be maintained.

The '386 patent discloses polyethers having a hydroxyl-functionality and an ethylenical unsaturated functionality. The polyether can be prepared for example by propoxylation of hydroxypropyl methacrylate ('386 patent, column 9, lines 32-37). The reference is not directed to, and does not teach or suggest, hydrogel-forming polymers. Importantly, the polyethers contain only one acryl group and *no* allyl group, in contrast to the claims wherein an internal crosslinker for the hydrogel-forming polymer requires at least 3 ethylenically unsaturated groups, and an allyl *and* an acryl group.

In view of these differences between the '386 patent disclosure and the present claims, a rejection of claims 5 and 8-12 as being anticipated by the '386 patent cannot be maintained.

The '425 patent is directed to hydrogel-forming polymers internally crosslinked with di- and tri-functional compounds disclosed at column 5, lines 33-65. Preferred crosslinkers include compounds containing three or four allyl groups (column 5, lines 59-60). However, the '425 patent fails to teach or suggest any internal crosslinker containing an allyl group *and* an acryl group.

In view of the difference between the '425 patent disclosure and the present claims, a rejection of claims 5 and 8-12 as being anticipated by the '425 patent cannot be maintained.

The '710 patent is directed to hydrogel forming polymers wherein (meth)acrylate esters of alkoxylated (meth)allyl alcohols can be used as an internal crosslinker (column 7, line 67 through column 8, line 3). These crosslinkers contain two ethylenically unsaturated groups as opposed to the three to ten ethylenically unsaturated

groups recited in the claims. In addition, the disclosed (meth)acrylate ester of alkoxylated (meth)allyl alcohols do not contain the radical A recited in the internal crosslinker of the present claims.

In view of the differences between the '710 patent disclosure and the present claims, a rejection of claims 5 and 8-12 as being anticipated by the '710 patent cannot be maintained.

In summary, claims 5 and 8-12 cannot be anticipated by any of the cited references because each reference differs in at least one respect from the claimed hydrogel-forming polymer. In addition, the examiner admits to a difference at page 5 of the Office Action by stating that the references do not disclose the compound of formula (I) in claim 1. Therefore, it is submitted that all rejections under 35 U.S.C. §102 should be withdrawn.

Claims 5 and 8-12 also stand rejected under 35 U.S.C. §103 as being obvious over WO '496 or EP '507 or WO '159 or WO '237 or the '816 patent or the '386 patent or the '425 patent or the '710 patent. Applicants traverse these rejections.

To establish a *prima facie* case of obviousness, three requirements must be satisfied. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 127 S.Ct. 1727 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was *an apparent reason* to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to *identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements* in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (emphasis added, *KSR, supra*). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was

made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. In *re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

As articulated by the Court of Appeals for the Federal Circuit in *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc.*, 86 USPQ2d, 1196, 1201-2 (Fed. Cir. 2008):

"As this court has explained, however, a flexible TSM test remains the primary guarantee against a non-statutory hindsight analysis such as occurred in this case. *In re Translogic Tech., Inc.* 504 F.3d 1249, 1257 [84 USPQ2d 1929] (Fed. Cir. 2007) ("[A]s the Supreme Court suggests, a flexible approach to the TSM test prevents hindsight and focuses on evidence before the time of invention.)"

Each cited reference is cited *individually* against the claims, and each is discussed above together with the differences between *each* reference and the present claims, e.g., containing less than three ethylically unsaturated functionalities and/or failing to contain both allyl and acryl groups and/or failing to be directed to a hydrogel forming polymer.

Therefore, because each reference fails to teach or suggest all the limitations of the claims to a *prima facie* case of obviousness over each of these references cannot be sustained.

In addition, the examiner has identified *no* reason that would have prompted a person skilled in the art *in the relevant field* to combine the elements in the way the claimed invention does. First, some of the references are *not* in the relevant field, i.e., hydrogel-forming polymers. Second, the references disclose various internal crosslinkers, but do not contain any teachings a suggestions that would lead a person skilled in the art to a hydrogel-forming polymer internally crosslinked with a compound recited in claims 1, 2, or 3.

In addition, even if a *prima facie* case of obviousness should be established over any of the cited references, the presently claimed hydrogel-forming polymers exhibit unexpected results. In particular, hydrogel-forming polymers of the present invention have a balanced profile with respect to absorption capacity, gel strength, take up rate, and

extractables (specification, page 2, line 38 through page 3, line 2). This balanced profile is related to the internal crosslinker used to prepare the polymer.

The specification at pages 31-32 includes a Comparative Example and Examples 7-9. The Comparative Example utilizes 15-tuply ethoxylated trimethylolpropane triacrylate as the internal crosslinker. This crosslinker is of the type disclosed in cited WO '237, and contains three acryl functionalities. However, the crosslinker does not contain an allyl group.

Examples 7-9 are internally crosslinked with a crosslinker of the present invention, i.e., contain a total of three ethylenically unsaturated groups, i.e., two acryl groups and an allyl group. The table at page 34 of the specification shows that Examples 7-9 retained absorbency compared to the Comparative Example *and* a reduced amount of extractables by about 50% or more. The reduced amount of extractables shows that a crosslinker recited in the present claims hydrogel-forming polymer more efficiently polymerize the monomer such that the amount of low molecular weight oligomers and monomers (i.e., extractables) are reduced (specification, page 34, lines 14-16).

Accordingly, applicants demonstrate an unexpected and unpredictable result compared to the closest prior art, i.e., a crosslinker containing three acryl groups (comparative) vs. a crosslinker containing two acryl groups and an allyl group.

The examiner relies upon an inherency theory to support the obviousness rejection. However, each cited art reference omits an aspect of the invention such that a claimed internal crosslinker could not result, let alone *necessarily* result, i.e., omit a claimed A moiety, omit an allyl group, omit an acryl group, and/or contain less than three ethylenically unsaturated groups.

It is axiomatic that to support a rejection based on inherency, the examiner *must* provide evidence showing that any missing descriptive matter is *necessarily* present. Inherency cannot be established by probabilities or possibilities. See MPEP §2112 IV (pages 2100-57) stating:

"*In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient."

In this case, the missing descriptive matter is an internal crosslinker containing three or more ethylenically unsaturated groups which include *both* allyl *and* acryl groups.

For all the reasons set forth above, it is submitted that claims 5 and 8-12 would not have been obvious over any cited reference under 35 U.S.C. §103, and that the rejection should be withdrawn. It also is submitted that new claims 13-18 would not have been obvious over any of the cited references.

It is submitted that the application is in a scope and form for allowance. An early and favorable action on the merits is respectfully requested.

Should the examiner wish to discuss the foregoing, or any matter of form in an effort to advance this application toward allowance, the examiner is urged to telephone the undersigned at the indicated number.

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Respectfully submitted,

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